DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-19

December 18, 1998

Peter H. Wettermann, President/Owner
International Medical, Inc.
10061 Amberwood Road
Fort Myers, FL 33913

Dear Mr. Wettermann:

We are writing to you because on November 30 - December 3, 1998, FDA Investigator Ronald T. Weber, collected information that revealed serious regulatory problems involving sterile and non-sterile biopsy forceps, laparoscopic devices, and surgical cauterizers (Class II), which are developed, manufactured, and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices that are used to diagnose or treat medical conditions or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform with the Quality System (QS) Regulation for Medical Devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that your devices are adulterated within the meaning of section **501(h)** of the Act, in that the methods used in, or the facilities or controls used for the manufacture, packing, storage, or installation are not in conformance with the QS regulation. These violations include, but are not limited to the following:

DESIGN CONTROLS

Failure to establish and maintain procedures to control the design and development of devices in order to ensure that specified design requirements are met including: design and development, design planning, design output, design review, design verification, design validation, design transfer, design changes, and design history files.

QS REGULATIONS

1) Failure to establish and maintain adequate procedures to conduct quality audits, e.g., there are no written procedures covering process validation, corrective and preventive action, purchasing controls, and design controls. [21 CFR 820.22].

2) Failure to establish and maintain procedures to validate, document, review, approve, and implement changes to components, finished devices, labeling, packaging, manufacturing processes, and quality assurance tests, e.g., there are no records covering the validation and change control for the manufacture of the Model 7300 biopsy forceps (crimping v. laser weld procedures) to assure the change is effective and does not affect finished device performance; records covering the validation of the EtO sterilization system fail to contain an assay of spore strips, record of bioburden testing, calibration of equipment; failure to conduct validation in accordance with specified protocols and manufacturing procedures (use of 40 forcep units v. 50 that are packed for standard sterilization runs) and for package integrity of heat sealed Tyvek bags; and failure to assure changes in manufacturer's instructions (removal of humidichip) does not adversely affect the EtO sterilization system and on the performance of the devices to meet their specifications. [21 CFR 820.75]

3) Failure to document and maintain records of incoming component testing, in-process testing, and finished device testing that assure all products meet specifications either for manufacturing or prior to release to distribution. [21 CFR 820.80]

4) Failure of management to assure that all quality assurance tests and reviews are appropriate and adequate, that adequate resources and adequately trained personnel are assigned to conduct quality assurance tasks, e.g., package integrity after EtO sterilization is not determined and training records are not maintained documenting that personnel have the training, experience, and expertise to perform these tasks. [21 CFR 820.20]

5) Failure to establish and maintain adequate purchasing control procedures, e.g., current procedures do not require documented evaluations and selections of potential vendors based on established criteria, there are no contracts between International Medical and vendors providing for notification of changes in products or services that may adversely affect the quality of the finished device. [21 CFR 820.50]

The investigator also discussed with you and Mr. Paul A. Duddy, General Manager, the failure to report a complaint your firm received from [redacted] on April 29, 1998. The complaint, with attached MedWatch form, reported that a biopsy forcep tip had fallen off in a patient and required physician intervention. The complaint should have been reported as an MDR, but was not. This complaint should be reported as an MDR as soon as possible.

This letter is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the List of Observations (FDA-483) issued to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the awards of contracts. Additionally, no premarket submissions for devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of any steps you may have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed, (2) any documentation indicating the correction has been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407)475-4728.

Sincerely,

Edward R. Rettus Jr.

Douglas D. Tolen
Director, Florida
District